Duke University
Durham, North Carolina 27705

Institutional Animal Care & Use Committee
Campus Mail: Hock Plaza Box 2724
US Mail: 2424 Erwin Road; Suite 1104; Durham, NC 27705

Voice: 919.668.6720
Fax: 919.668.6725
http://vetmed.duhs.duke.edu

November 17, 2005

Dr. Richard L. Auten
Box 3373, DUMC

Dear Dr. Auten:

Re: "DISPARITIES IN FETAL ATMOSPHERIC EXPOSURE AND POST-NATAL LUNG DEVELOPMENT"
Protocol Registry Number A329-05-11

On November 17, 2005, the Duke University & Duke University Medical Center Institutional Animal Care and Use Committee (IACUC) reviewed and approved the above referenced protocol. The terms of this approval are as follows:

Approval Period: The date of approval for this protocol is November 17, 2005. Approval is for three years from this date, contingent upon annual reporting of protocol activity.

Approved Number of Animals: The species and numbers of animals approved for the full three-year period of this study are: 48 adult and 240 Mouse pups

Annual Reporting: Continued approval during this three year period is contingent upon the timely submission of Annual Review reports. The report forms are available / downloadable from the animal program website. The web address is: http://vetmed.duhs.duke.edu/animal/ Annual Review reports must be received and approved by the anniversary date of the original approval for continued approval of your protocol. The Office of Animal Welfare Assurance will alert you to the approaching annual report date so that you may respond promptly with your report.

Renewal of the Protocol: Federal requirements dictate a complete new review of continuing studies at the end of the three-year approval period. If you desire continuation of the protocol beyond the current (3 year) approval, you will need to submit a renewal application for review and approval by the IACUC. This renewal application must be a de novo submission; the IACUC cannot consider the current document in its present form. The Office of Animal Welfare Assurance will alert you at approximately the 32nd month of your current approval period. At that time, please prepare a new application for animal use and submit it before the applicable deadline. Please use the most current protocol template, also available on the animal program web site. Without renewed IACUC approval, ongoing research under the retiring protocol must be halted. Any remaining animals must be: 1) turned over to DLAR for disposal; 2) transferred to another approved protocol; or 3) transferred to the DLAR holding protocol (you cannot use any animals in active research being held on the DLAR protocol). With IACUC approval of a new protocol submission, a new protocol registry number will be assigned. Any cage cards for existing cages of animals should be transferred to the new protocol number. You will need to contact DLAR so that they can prepare cage cards for you, and your staff should replace the retiring cage cards with the cards that reflect the new registry information. Failure to promptly transfer the animals to the new protocol registry number may result in the placement of new cage cards by DLAR staff with assessment of a service charge.

Principal Investigator Responsibilities: Use of animals for research, testing, teaching, production, or exhibition must be in accordance with the USDA Animal Welfare regulations, PHS Policy on Humane Care and Use of Laboratory Animals, the NIH/NRC Guide for the Care and Use of Laboratory Animals, AAALAC accreditation guidelines, and Duke University Institutional Animal Care and Use Committee (DUIACUC) care and use policies. These references materials are available for review on the animal program web site at: http://vetmed.duhs.duke.edu/animal/

Personnel Performing Work Under This Approval: All personnel working with animals must be enrolled in an appropriate occupational health and safety program. The Duke University Occupational Health Program is available to all Duke students, employees and staff. Enrollment forms are available from the animal program web site. If you determine that additional personnel should be associated with this approved activity, then you must notify the IACUC of these personnel changes to the protocol, including changes in roles for existing personnel, and the addition or deletion of animal care and use personnel. These changes must be approved by the IACUC before personnel can begin work with animals. Except for a change in the Principal Investigator, a Minor Amendment form should be used for this purpose, also available on the animal program web site at http://vetmed.duhs.duke.edu/animal/

Amendment of the protocol: Approval for any change to the protocol (whether Significant or Minor) must be obtained from the IACUC prior to implementation of the change. Forms for requesting either a Minor or Significant Change are available / downloadable from the animal program web site at http://vetmed.duhs.duke.edu/animal/

Post-Approval Monitoring of Protocols: Duke University and Duke University Medical Center is fully committed to quality animal care and compassionate animal use in an atmosphere of progressive animal based research. To fulfill our legal, ethical, and moral obligations under federal regulations, funding commitment, and accreditation principles, the institution will perform post-approval monitoring of approved activities:

A. All animal use areas are inspected every 6 months by a subcommittee of the IACUC. When this activity is required, the Office of Animal Welfare Assurance may contact your staff and determine a convenient schedule to visit your laboratory. While these visits are usually announced, the IACUC has the obligation to perform unannounced visits on occasion.

B. A second method of meeting public expectation of animal research management, is through the Office of Animal Welfare Assurance's Compliance Liaison Program (CLP). These individuals assure research integrity for the institution while facilitating your research needs and goals. The institution's Liaisons may perform either scheduled or un-announced visits to the animal research environment. While the goal is a fully compliant audit, any correction of issues discovered during a compliance visit will be facilitated by the CLP. The Liaisons will partner with your laboratory to keep your research fully productive and your adherence to the plethora of rules and regulations fully engaged.

At any time, please visit the animal program web site for the latest in program information. You are also encouraged to use the IACUC's Email address IACUC@Duke.edu for all of your correspondence and communication needs.

Please do not hesitate to contact me if there is anything that we can do to facilitate your research.

Sincerely,

(b) (6) [redacted]

Lee Tyrey, Ph.D.
Chairman, IACUC

Duke University
Institutional Review Board for the Protection of Human Subjects in Non-Medical Research
FWA No. 00000265
Notice of Approval of Protocol Renewal

Investigator(s):	Marie-Lynn Miranda, Trish McMillan
Advisor:	
Protocol Title:	Mapping Disparities in Birth Outcomes
Protocol Number:	1081 (Previous Number)
Approval Date:	Thursday, October 26, 2006
Expiration Date:	Sunday, November 18, 2007
Sponsor:	NIH
Sponsor Number (if applicable):	1-P20-RR020782-01

Please note: Approval is contingent upon maintaining certification to conduct research with human subjects.

In conducting research under this protocol, the researcher agrees:

-- to seek written approval from the IRB before any changes are made to the protocol, including, but not limited to amendments to procedures, recruitment strategies, subject population, instruments, and the informed consent process. The form, Request to Amend an Approved Protocol, is available at <http://www.ors.duke.edu/irb/irbform.htm>

-- to report immediately to the IRB Administrator any problems, including unanticipated risks to the subjects

-- to retain signed consent forms and other research records in accordance with Duke's Data Retention Policy (5 years) <http://www.ors.duke.edu/policies/datarete.htm>

-- to notify the Office for Protection of Human Subjects at ors-info@duke.edu when the research is completed

Renewing the Protocol

Unless otherwise informed by the IRB, the renewal process must be completed within twelve months. A schedule of IRB meetings is available at <http://www.ors.duke.edu/irb/dates>.

Reminder notices will be provided as the end of the approval period approaches. If a renewal deadline is missed, there's no approval in place until the renewal request has been acted upon. Without an approval in place, all activities associated with the research must be suspended.

The form, Request to Renew an Approved Protocol, is available at <http://www.ors.duke.edu/irb/irbform.htm>

Generated by Admin on 10/27/2006 11:26:53 AM

Notice of Approval of Protocol Renewal
Protocol # 1081

Investigator(s):	Marie-Lynn Miranda
Advisor:	
Protocol Title:	Mapping Disparities in Birth Outcomes
Protocol Number:	1081
Approval Date:	September 15, 2011
Expiration Date:	September 17, 2012

Renewal Approval Notice received via e-mail, as follows:

From: IRB ADMINISTRATOR [mailto:ors-info@duke.edu]
Sent: Thursday, September 15, 2011 11:10 AM
To: Alicia Overstreet Galeano; Claire Osgood; Pamela Maxson, Ph.D.; Lynne Messer, Ph.D.; Marie Lynn Miranda, Ph.D.; Victoria Shelus; Ben Strauss; Melissa Tosiano; Brian Neelon; Edwards, Sharon; Reiter, Jerry; Joshua Tootoo; Myers, Evan
Cc: Alejandro Martinez
Subject: [IRB]Notice of Approved Renewal

Protocol : [1081] Mapping Disparities in Birth Outcomes

Researcher(s) :
Jerry Reiter(Research Staff)
Pamela Maxson(Research Staff)nullnull
Joshua Tootoo(Research Staff)null
Victoria Shelus(Graduate Student Researcher)
Benjamin Strauss(Research Staff)
Lynne Messer(Researcher)nullnull
Alicia Overstreet(Research Staff)
Brian Neelon(Research Staff)
Sharon Edwards(Research Staff)
Evan Myers(Researcher)
Marie-Lynn Miranda(Researcher)null
Claire Osgood(Manager)
Melissa Tosiano(Graduate Student Researcher)

Book 3

Human Health

Expiration Date : 9/17/2012

Your request to renew an approved protocol has been approved.

As described in your original notice of Protocol Approval, researchers agree to:

- Secure approval before making any changes to the protocol, such as adding another subject population, revising procedures, modifying the informed consent process, or replacing or adding investigators.

The form, **Request to Amend an Approved Protocol,** can be found at:
http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Renew the protocol within twelve months.

  The form, **Request to Renew an Approved Protocol**, can be found at:
  http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Report any unanticipated risks to the research subjects or deviations from the procedures described in the protocol as soon as they are identified. Report to Lorna Hicks at lorna.hicks@duke.edu.

- Notify the IRB staff at ors-info@duke.edu when the research is completed.

Duke University
Durham, North Carolina 27705

Institutional Animal Care & Use Committee
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Voice: 919.668.6720
Fax: 919.668.6725
http://vetmed.duhs.duke.edu

September 23, 2011

Dr. Richard Auten
Box 3373, DUMC

Dear Dr. Auten,

Re: PERINATAL EXPOSURE DISPARITY AND RESPIRATORY HEALTH
Protocol Registry Number A251-11-09

On September 22, 2011, the Duke University & Duke University Medical Center Institutional Animal Care and Use Committee (IACUC) reviewed and **approved** the above referenced protocol. The terms of this approval are as follows:

Approval Period: The date of approval for this protocol is September 22, 2011. Approval is for three years from this date, contingent upon annual reporting of protocol activity.

Approved Number of Animals: The species and numbers of animals approved for the full three-year period of this study are:

1968 ADULT MICE, 240 EMBRYOS

Annual Reporting: Continued approval during this three year period is contingent upon the timely submission of Annual Review reports. The report forms are available / downloadable from the animal program website. The web address is: http://vetmed.duhs.duke.edu/index_of_forms.htm. Annual Review reports must be received and approved by the anniversary date of the original approval for continued approval of your protocol. All personnel listed on the approved protocol must be current on employee health surveillance and training requirements; supervisors can assess the status of employees health and safety status on the OESO web site (see Management Reports). The Office of Animal Welfare Assurance will alert you to the approaching annual report date so that you may respond promptly with your report.

Protocol Access: Information contained in your animal use protocol is considered privileged. The policy that governs access to the file can be viewed here: http://vetmed.duhs.duke.edu/documents/iacuc/pdf/policy_on_IACUC_review_and_approval_practices-protection_of_protocol_information.pdf

Renewal of the Protocol: Federal requirements dictate a complete new review of continuing studies at the end of the three-year approval period. If you desire continuation of the protocol beyond the current (3 year) approval, you will need to submit a renewal application for review and approval by the IACUC. This renewal application must be a de novo submission; the IACUC cannot consider the current document in its present form. The Office of Animal Welfare Assurance will alert you at approximately the 32nd month of your current approval period. At that time, please prepare a new application for animal use and submit it before the applicable deadline. Please use the most current protocol template, also available on the animal program web site. Without renewed IACUC approval, ongoing research under the retiring protocol must be halted. Any remaining animals must be: 1) turned over to DLAR for disposal; 2) transferred to another approved protocol; or 3) transferred to the DLAR holding protocol (you cannot use any animals in active research being held on the DLAR protocol). With IACUC approval of a new protocol submission, a new protocol registry number will be assigned. Any cage cards for existing cages of animals should be transferred to the new protocol number. You will need to contact DLAR so that they can prepare cage cards for you, and your staff should replace the retiring cage cards with the cards that reflect the new registry information. Failure to promptly transfer the animals to the new protocol registry number may result in the placement of new cage cards by DLAR staff with assessment of a service charge.

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Personnel Performing Work Under This Approval: All personnel working with animals must be enrolled in an appropriate occupational health and safety program. The Duke University Occupational Health Program is available to all Duke students, employees and staff. Enrollment forms are available from the animal program web site. If you determine that additional personnel should be associated with this approved activity, then you must notify the IACUC of these personnel changes to the protocol, including changes in roles for existing personnel, and the addition or deletion of animal care and use personnel. These changes must be approved by the IACUC before personnel can begin work with animals. Except for a change in the Principal Investigator, a Minor Amendment form should be used for this purpose, also available on the animal program web site at http://vetmed.duhs.duke.edu/index_of_forms.htm.

Amendment of the protocol: Approval for any change to the protocol (whether Significant or Minor) must be obtained from the IACUC prior to implementation of the change. Forms for requesting either a Minor or Significant Change are available / downloadable from the animal program web site at http://vetmed.duhs.duke.edu/index_of_forms.htm.

Post-Approval Monitoring of Protocols: Duke University and Duke University Medical Center is fully committed to quality animal care and compassionate animal use in an atmosphere of progressive animal based research. To fulfill our legal, ethical, and moral obligations under federal regulations, funding commitment, and accreditation principles, the institution will perform post-approval monitoring of approved activities:

A. All animal use areas are inspected every 6 months by a subcommittee of the IACUC. When this activity is required, the Office of Animal Welfare Assurance may contact your staff and determine a convenient schedule to visit your laboratory. While these visits are usually announced, the IACUC has the obligation to perform unannounced visits on occasion.

B. A second method of meeting public expectation of animal research management is through the Office of Animal Welfare Assurance's Compliance Liaison Program (CLP). These individuals assure research integrity for the institution while facilitating your research needs and goals. The institution's Liaisons may perform either scheduled or un-announced visits to the animal research environment. While the goal is a fully compliant audit, any correction of issues discovered during a compliance visit will be facilitated by the CLP. The Liaisons will partner with your laboratory to keep your research fully productive and your adherence to the plethora of rules and regulations fully engaged.

At any time, please visit the animal program web site for the latest in program information. You are also encouraged to use the IACUC's Email address IACUC@Duke.edu for all of your correspondence and communication needs.

Please do not hesitate to contact me if there is anything that we can do to facilitate your research.

Sincerely,

(b) (6) [redacted]

Laura P. Hale, M.D., Ph.D.
Chairman, IACUC

Notice of Approval of Protocol
Protocol # HUM00054645

Investigator(s):	Marie-Lynn Miranda
Protocol Title:	Mapping Disparities in Birth Outcomes
Protocol Number:	HUM00054645
Approval Date:	October 11, 2011
Expiration Date:	October 10, 2012

Renewal Approval Notice received via e-mail, as follows:

Health Sciences and Behavioral Sciences Institutional Review Board • 540 East Liberty Street, Suite 202, Ann Arbor, MI 48104-2210 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

---

To: Marie Lynn Miranda

From:

Richard Redman

Cc:

Simone	Gray
Joshua	Tootoo
Claire	Osgood
Brian	Neelon
Sharon	Edwards
Ben	Strauss
Evan	Raczkowski
Howard	Chang
Pamela	Maxson
Marie Lynn	Miranda
Rebecca	Anthopolos

Subject:Initial Study Approval for [HUM00054645]

SUBMISSION INFORMATION:
Study Title: Mapping Disparities in Birth Outcomes
Full Study Title (if applicable):
Study eResearch ID: HUM00054645
Date of this Notification from IRB:10/11/2011
Review:Expedited
Initial IRB Approval Date: 10/11/2011
Current IRB Approval Period:**10/11/2011 - 10/10/2012**
Expiration Date: Approval for this expires at **11:59 p.m. on 10/10/2012**

UM Federalwide Assurance (FWA): FWA00004969 expiring on 11/17/2011
OHRP IRB Registration Number(s): IRB00000245

Approved Risk Level(s):

Name	Risk Level
HUM00054645	No more than minimal risk

NOTICE OF IRB APPROVAL AND CONDITIONS:
The IRB HSBS has reviewed and approved the study referenced above. The IRB determined that the proposed research conforms with applicable guidelines, State and federal regulations, and the University of Michigan's Federalwide Assurance (FWA) with the Department of Health and Human Services (HHS). You must conduct this study in accordance with the description and information provided in the approved application and associated documents.

APPROVAL PERIOD AND EXPIRATION:
The approval period for this study is listed above. Please note the expiration date. If the approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

APPROVED STUDY DOCUMENTS :
You must use any date-stamped versions of recruitment materials and informed consent documents available in the eResearch workspace (referenced above). Date-stamped materials are available in the "Currently Approved Documents" section on the "Documents" tab.

RENEWAL/TERMINATION:
At least two months prior to the expiration date, you should submit a continuing review application either to renew or terminate the study. Failure to allow sufficient time for IRB review may result in a lapse of approval that may also affect any funding associated with the study.

AMENDMENTS:
All proposed changes to the study (e.g., personnel, procedures, or documents), must be approved in advance by the IRB through the amendment process, except as necessary to eliminate apparent immediate hazards to research subjects. Should the latter occur, you must notify the IRB Office as soon as possible.

AEs/ORIOs:
You must inform the IRB of all unanticipated events, adverse events (AEs), and other reportable information and occurrences (ORIOs). These include but are not limited to events and/or information that may have physical, psychological, social, legal, or economic impact on the research subjects or other.

Investigators and research staff are responsible for reporting information concerning the approved research to the IRB in a timely fashion, understanding and adhering to the reporting guidance (http://www.med.umich.edu/irbmed/ae_orio/index.htm), and not implementing any changes to the research without IRB approval of the change via an amendment submission. When changes are necessary to eliminate apparent immediate

hazards to the subject, implement the change and report via an ORIO and/or amendment submission within 7 days after the action is taken. This includes all information with the potential to impact the risk or benefit assessments of the research.

SUBMITTING VIA eRESEARCH:
You can access the online forms for continuing review, amendments, and AEs/ORIOs in the eResearch workspace for this approved study (referenced above).

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at: www.research.umich.edu/hrpp.

(b) (6)

[redacted]

Richard Redman
Chair, IRB HSBS

DukeMedicine
Institutional Review Board for Clinical Investigations

IRB NOTIFICATION OF CONTINUING REVIEW APPROVAL

Continuing Review ID: CR5_Pro00007633
Principal Investigator: Geeta Swamy
Protocol Title: Mapping Disparities in Pregnancy Outcomes: Impact of Psychosocial, Environmental, and Genetic Factors
Sponsor/Funding Source(s): US Environmental Protection Agency (USEPA)
Federal Funding Agency ID: RD-83329301-0
Date of Declared Concordance with federally funded grant, if applicable: N/A

The Duke University Health System Institutional Review Board for Clinical Investigations has conducted the following activity on the study cited above:

Activity: Continuing Review **Review Type:** Expedited
Review Date: 5/1/2012
Issue Date: 5/2/2012
Anniversary Date: 5/30/2012
Expiration Date: 5/30/2013

DUHS IRB approval encompasses the following specific components of the study:

Protocol, version/date:	--
Summary, version/date:	--2/15/2010
Consent form reference date:	--closed
Investigator Brochure, version/date:	--
Pediatric Risk Category:	-- 45CFR46.404 and 21 CFR 50.51 as applicable
Other:	--

The DUHS IRB has determined the specific components above to be in compliance with all applicable Health Insurance Portability and Accountability Act ("HIPAA") regulations.

This study expires at 12 AM on the Expiration Date cited above. At that time, all study activity must cease. If you wish to continue specific study activities directly related to subject safety, you must immediately contact Dr. John Falletta or Jody Power. Continuing review submissions (renewals) must be received by the DUHS IRB office 60 to 45 days prior to the Expiration Date.

No change to the protocol, consent form or other approved document may be implemented without first obtaining IRB approval for the change. Any proposed change must be submitted as an amendment. If necessary in a life-threatening situation, where time does not permit your prior consultation with the IRB, you may act contrary to the protocol if the action is in the best interest of the subject. You must notify the IRB of your action within five (5) working days of the event.

The Duke University Health System Institutional Review Board for Clinical Investigations (DUHS IRB), is

duly constituted, fulfilling all requirements for diversity, and has written procedures for initial and continuing review of human research protocols. The DUHS IRB complies with all U.S. regulatory requirements related to the protection of human research participants. Specifically, the DUHS IRB complies with 45CFR46, 21CFR50, 21CFR56, 21CFR312, 21CFR812, and 45CFR164.508-514. In addition, the DUHS IRB complies with the Guidelines of the International Conference on Harmonization to the extent required by the U. S. Food and Drug Administration.

DUHS Institutional Review Board
2424 Erwin Rd | Suite 405 | Durham, NC | 919.668.5111
Federalwide Assurance No: FWA 00009025

From: IRB ADMINISTRATOR [mailto:ors-info@duke.edu]
Sent: Monday, September 17, 2012 4:22 PM
To: Marie Miranda (mmiranda); Claire Osgood; Brian Neelon; Pamela Maxson, Ph.D.; Reiter, Jerry; Myers, Evan ; Ben Strauss
Cc: Holly Williams-Stafford
Subject: 1081 - [IRB]Notice of Approved Renewal

Protocol : [1081] Mapping Disparities in Birth Outcomes

Researcher(s) :
Evan Myers(Researcher)nullnullnull
Claire Osgood(Manager)null
Jerry Reiter(Research Staff)null
Pamela Maxson(Research Staff)nullnullnullnullnull
Marie-Lynn Miranda(Researcher)null
Benjamin Strauss(Research Staff)null
Brian Neelon(Research Staff)

Expiration Date : 9/16/2013

Your request to renew an approved protocol has been approved.

As described in your original notice of Protocol Approval, researchers agree to:

- Secure approval before making any changes to the protocol, such as adding another subject population, revising procedures, modifying the informed consent process, or replacing or adding investigators.

  The form, **Request to Amend an Approved Protocol,** can be found at:
  http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Renew the protocol within twelve months.

  The form, **Request to Renew an Approved Protocol**, can be found at:
  http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Report any unanticipated risks to the research subjects or deviations from the procedures described in the protocol as soon as they are identified. Report to Lorna Hicks at lorna.hicks@duke.edu.
- Notify the IRB staff at ors-info@duke.edu when the research is completed.

From: IRB ADMINISTRATOR [ors-info@duke.edu]
Sent: Friday, September 13, 2013 9:55 AM
To: Marie Miranda (mmiranda); Claire Osgood; Brian Neelon; Pamela Maxson; Reiter, Jerry; Myers, Evan ; Ben Strauss
Cc: Alejandro Martinez
Subject: [IRB]Notice of Approved Renewal

Protocol : [1081] Mapping Disparities in Birth Outcomes

Researcher(s) :
Marie-Lynn Miranda(Researcher)nullnullnullnullnullnull
Claire Osgood(Manager)
Evan Myers(Researcher)null
Jerry Reiter(Research Staff)null
Brian Neelon(Research Staff)
Pamela Maxson(Research Staff)null
Benjamin Strauss(Research Staff)

Expiration Date : 9/16/2014
Your request to renew an approved protocol has been approved.

As described in your original notice of Protocol Approval, researchers agree to:

- Secure approval before making any changes to the protocol, such as adding another subject population, revising procedures, modifying the informed consent process, or replacing or adding investigators.

  The form, **Request to Amend an Approved Protocol,** can be found at:
  http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Renew the protocol within twelve months.

  The form, **Request to Renew an Approved Protocol**, can be found at:
  http://www.ors.duke.edu/Research-with-Human-Subjects/forms

- Report any unanticipated risks to the research subjects or deviations from the procedures described in the protocol as soon as they are identified. Report to Lorna Hicks at lorna.hicks@duke.edu.

- Notify the IRB staff at ors-info@duke.edu when the research is completed.

Request for Protocol Approval for Secondary Analysis of Existing Data

> **Existing Data** is in existence at the time the research is proposed. The data may be in the form of data sets, but may also be in the form of interview notes or audio- or video tapes.

This form is to be used when existing data about human subjects, **with identifiers**, will be received by an investigator for secondary analysis. It should be used for all types of review. After reading the guidelines for submitting a protocol for secondary analysis of existing data, consulting with the IRB staff if necessary, please check the type of review you are requesting.

Screening for Exemption: __ Expedited Review: **_X_** Full Review: ___

There are three parts to this request:

A. Investigator and Project Information
B. Investigator, Advisor, and Department/School Assurances
C. Project Description

A. Investigator and Project Information

Investigator: **Dr. Marie Lynn Miranda**

Status: [**X**] Faculty [ ] Graduate Student [ ] Undergraduate [ ] Other:_____

Department/School: **Nicholas School of the Environment and Earth Sciences**

e-mail: **mmiranda@duke.edu** Phone: **919.613.8023** Campus PO Box No. **90328**

Faculty Advisor for Graduate and Undergraduate Students:

_____

e-mail:_mmiranda@duke.edu____ Phone: _613-8023 Campus PO Box No. _90328____

Project Title: **Duke Center for Geospatial Medicine**

Source of Funding: **The National Institutes of Health Roadmap Initiative**

(If externally funded, submit a copy of the application or the award, including the current renewal if applicable.)

Proposal/Grant No. for Federally funded research: **1-P20-RR020782-01**

B. Assurances

(Original signatures are required for final approval.)

Investigator(s) Assurance:

I certify to the following:

1. The research will not be initiated until written approval is secured from the IRB. **(Note: Approval will not be provided unless the investigator(s) certification to conduct research with human subjects is current, and if the investigator is a student, the advisor's certification is also current.)**
2. I will conduct this study as described in the approved protocol. If any changes are anticipated, I will contact the IRB staff prior to implementing the changes. I will contact the IRB staff immediately if any of the following events occur: unanticipated risks, findings during the study that would affect the risks or benefits, and adverse events.

_____ _____

Investigator Date

_____ _____

Investigator Date

Faculty Advisor Assurance (Required for Graduate or Undergraduate Student Research):

I certify that I have reviewed and approved the student(s) research plan. I assume responsibility for 1) ensuring that the student(s) conducting research are aware of their responsibilities as researchers, and 2) that the IRB will be immediately informed in the event of unanticipated risk, adverse events or findings during the study that would affect the risks or benefits of participation.

_____ _____

Advisor Date

_____ _____

Advisor Date

Approval of the Department Chair or School Dean:

_____ Date _____

Chair or Dean

==========

APPROVAL: _____ Date _____

Human Subjects Administrator or IRB Member

Part C: Project Description

Please prepare a narrative that addresses the following topics.

1. The purpose of the research
2. A description of the data
3. The source of the data
4. Requirements of the data supplier, if any
5. A description of confidentiality procedures. If the access to the data is governed by a data use agreement, provide the most recent, signed, copy of the agreement.

If informed consent must be secured, for example for the use of video tapes, identify the subject populations, describe the consent process, and attach the proposed Informed Consent form.

****

Purpose of Research

The purpose of this research is to examine a wide range of maternal and child outcomes associated with pregnancy in North Carolina during the period from 1999 to 2003. These outcomes include maternal weight gain and maternal and child outcomes, fetal growth restriction, race-based differences in birth outcomes, and geographic patterns in birth outcomes. The initial use of the data will involve exploratory analysis related to the work of the Duke Center for Geospatial Medicine (CGM). This initial use is expected to lead to more advanced CGM research, with broad theoretical and applied applications. Detailed information on the Center for Geospatial Medicine's research agenda is available at the CGM website, (see http://www.nicholas.duke.edu/cgm/).

Data Description

These data are referred to as North Carolina Detailed Birth Records 1999 – 2003 and contain detailed birth data information for all births in North Carolina from 1999 to 2003. The data are in the form of five SAS format text files, one for each year of data. Rather than attempt to summarize these data, please see the attached full description of all data attributes (see attached document, 1999 Detail Birth File Description). These data attributes are identical for all five datasets.

Data Source

Data have been provided by the North Carolina State Center for Health Statistics (NCSCHS). The NCSCHS web site (http://www.schs.state.nc.us/SCHS/index.html) provides detailed information on the Center.

Requirements of Data Supplier

The data supplier has stipulated the following requirements (taken directly from the data sharing agreement):

1. Measures will be taken to ensure the security of the data, including but not limited, to password protection for all computer storing birth data
2. The data set will only be disclosed to the contractor performing the data analysis. Under no circumstances will additional copies of the data set containing identifiable health information be disclosed to anyone other then the undersigned without prior approval by the Director of the State Center for Health Statistics of the State Health Director
3. By signing this agreement, the undersigned agrees to supply SCHS with a copy of any reports/analyses published or released using this data
4. The contractor agrees to return or destroy the tape/CD containing the birth data file after the study is completed, or no later than by a mutually agreed designated time, whichever comes first.

Confidentiality Procedures

Data will be managed by staff who work for Professor Marie Lynn Miranda within the Children's Environmental Health Initiative (CEHI). CEHI has extensive experience in managing and securing confidential data. For more information on CEHI, see the Initiative's website at http://www.nicholas.duke.edu/cehi/. Dr. Miranda is the Director of CEHI, as well as the PI on the CGM grant. The staff that will work with the birth certificate data are: Chris Mankoff, Associate in Research; M. Alicia Overstreet, Data Manager; Sharon Edwards, Associate in Research; and Brack Hale, Post-Doctoral Associate. All of these individuals are certified through ORS to conduct research with human subjects.

All sensitive digital data at CEHI reside on a completely private, (i.e., with no access to the Internet), password-protected network to ensure that data are inaccessible to unauthorized users. The CEHI data server and all workstations connected to the server are kept in secure, locked locations. All sensitive hard copy data are kept in secure rooms and shredded at time of disposal.

In addition to the above procedures, CEHI conforms to all the standards and procedures outlined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). A signed copy of the data use agreement between the North Carolina State Center for Health Statistics and CEHI is attached to this document. This agreement explicitly outlines the data confidentiality procedures to be used with these data.